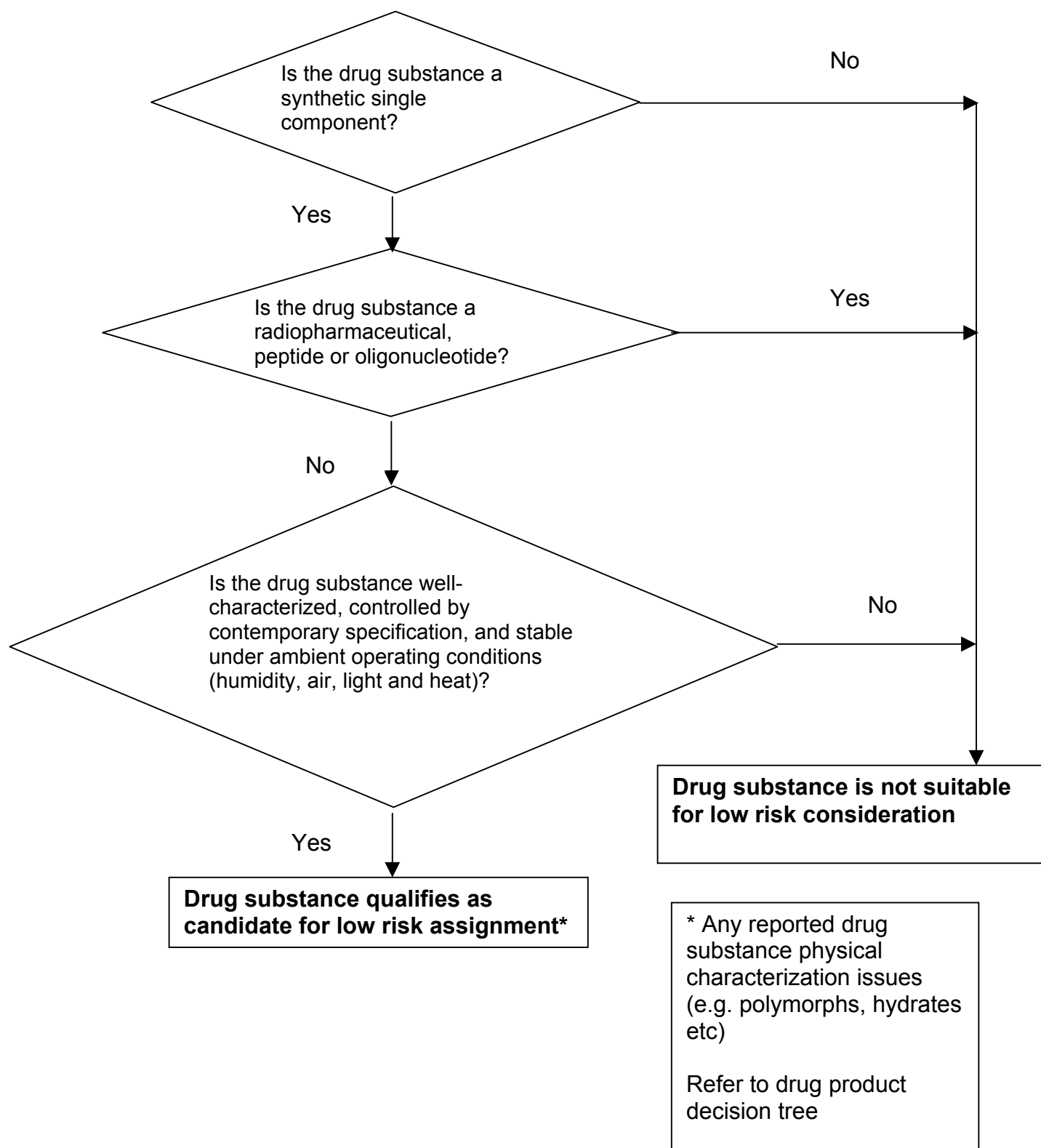
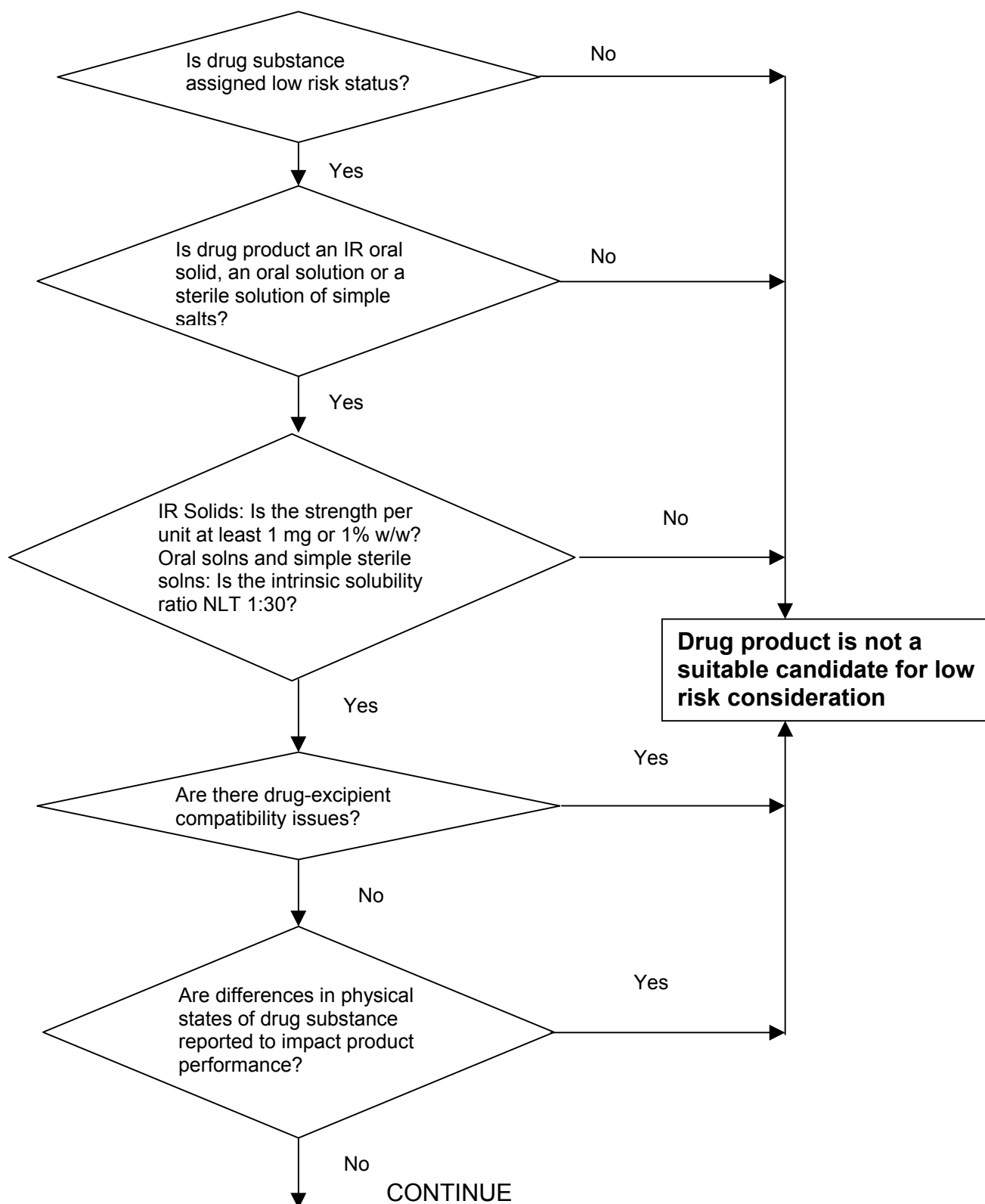


ATTACHEMENT #1

TOPIC: RISK-BASED CMC REVIEW

DECISION TREE #1: DRUG SUBSTANCE RISK ASSESMENT

DECISION TREE #2: LOW RISK DRUG PRODUCT ASSESSMENT:

DECISION TREE #2: LOW RISK DRUG PRODUCT ASSESSMENT (continued)

Continued from impact of physical state of drug substance on drug product

